Medicines & Healthcare products Regulatory Agency

EyeCee One and EyeCee One Crystal preloaded intraocular lenses (IOLs): update of previous quarantine advice after identification of likely cause, DSI/2023/007

Devices Details
Device Name: EyeCee One and EyeCee One Crystal preloaded intraocular lenses (IOLs)
Affected lot numbers/serial numbers: see Field Safety Notice
Manufactured by NIDEK and distributed by Bausch + Lomb

Summary
The MHRA is providing an update on the issue of increased intraocular pressure in patients implanted with EyeCee One preloaded and EyeCee One Crystal preloaded intraocular lenses.

New advice
This Device Safety Information replaces advice in DSI/2023/001, which should no longer be followed.

On 13 July 2023, NIDEK published an updated Field Safety Notice, which states that only EyeCee One and EyeCee One Crystal preloaded intraocular lenses (IOLs) manufactured between September 2021 and November 2022 are affected by a manufacturing problem that they attribute as the likely causal factor of increased intraocular pressure (IOP) in some patients. NIDEK has now recalled specific affected batches as listed in the Field Safety Notice.

The likely cause has now been identified and found to only affect those IOLs manufactured between September 2021 and November 2022. Therefore all other IOLs within their expiry date can now be removed from quarantine and used in patients, as they are unaffected by this issue.

Background to this safety issue
In January 2023, cases were reported of increased intraocular pressure in patients recently implanted with EyeCee One preloaded and EyeCee One Crystal preloaded IOLs.

NIDEK published a Field Safety Notice quarantining all EyeCee One and EyeCee One Crystal preloaded IOLs. The MHRA also published a Device Safety Information (DSI/2023/001) quarantining these devices. On 1 February, we issued a National Patient Safety Alert (NatPSA/2023/003/MHRA) asking that all patients implanted with these devices since October 2022 be recalled to have their intraocular pressure checked.

Further advice on patient monitoring
Patients who were found to have normal intraocular pressure do not require further follow-up, as the increased pressure occurs in the period covered by general postoperative management after cataract surgery. They should continue to have regular sight tests with their optometrist. Patients who were found to have high intraocular pressure should continue to be seen by an appropriate specialist for treatment and monitoring.

For information and action by

- Ophthalmology
- Ophthalmic theatres

Instructions for Medical Device Safety Officer/Medication Safety Officer: Please circulate/forward to relevant departments.

Actions

- Identify the IOLs affected by the updated Field Safety Notice and follow the actions in the notice to retain these for manufacturer recall
- All other EyeCee One and EyeCee One Crystal preloaded IOLs within their expiry date can now be used.
- There are specific reporting arrangements for healthcare professionals to follow in each region. Healthcare professionals should report incidents:
    - in England and Wales to the Yellow Card scheme or via the Yellow Card app
    - in Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system
    - in Northern Ireland to the Northern Ireland Adverse Incident Centre and their local incident recording system

Actions for patients

The advice in this notice is aimed at the healthcare teams who are responsible for providing and monitoring lenses used in cataract surgery. If you or somebody in your care had cataract surgery recently and are concerned, please contact the hospital where you had surgery for advice.

If you received one of the affected EyeCee One preloaded and EyeCee One Crystal preloaded intraocular lenses (IOLs) you should have had your eye pressures checked in February 2023, as advised by NatPSA/2023/003/MHRA:

- If your intraocular pressure was found to be normal, you do not need to have additional monitoring. You should continue to attend your normal recommended sight tests with your optometrist at least every 2 years.
- If your intraocular pressure was found to be high, continue to attend appointments with the specialist for treatment and monitoring.

Patients and caregivers in the UK can report suspected adverse reactions to medical devices to the Yellow Card scheme.

Stakeholder engagement

The MHRA has consulted with NHS England and representatives from the Scottish and Welsh Governments and the Department of Health Northern Ireland. The MHRA has also consulted with the Royal College of Ophthalmologists and the College of Optometrists.

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